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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,902	06/13/2001	Y Tom Tang	PF-0577 USN	3561
27904	7590	02/13/2004	EXAMINER	
INCYTE CORPORATION 3160 PORTER DRIVE PALO ALTO, CA 94304			WAX, ROBERT A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/763,902	Applicant(s) TANG ET AL.	
	Examiner Robert A. Wax	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-39 is/are pending in the application.
- 4a) Of the above claim(s) 21,25,27,32-34,37 and 38 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-31,35,36 and 39 is/are allowed.
- 6) ☒ Claim(s) 22-24 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11032003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in Paper No. 04222003 is acknowledged. The traversal is on the ground(s) that DNA and protein share a special technical feature since the examples in the PCT Administrative Rules say so. This is not found persuasive because there is no per se rule as to what shares a special technical feature and what does not. The structure of the DNA is extremely different from the structure of the protein and both have widely divergent activities. For these reasons, the DNA and protein lack a special technical feature. Evidence of this was discussed previously where Kain et al. taught a polynucleotide substantially identical to SEQ ID No. 1. Where the sequence exists in the prior art, unity of invention is lacking. The cancellation of SEQ ID No. 1 from the claims does not eliminate the finding.

The requirement is still deemed proper and therefore continues to be FINAL.

Part of the arguments is, however, convincing and the examiner hereby rejoins composition claims 32 and 34 with claim 21. The question of rejoinder of method claims 36, 37 and 38 will be taken up when the protein claims are examined, should a divisional application be filed.

Information Disclosure Statement

2. The information disclosure statement filed November 10, 2003 has been considered. Please see the attached initialed PTO-1449.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 22 and 26 are again rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 22 and 26 recite the limitation "claim 21". However, claim 21 remains withdrawn as directed to a non-elected invention and therefore there is insufficient antecedent basis for this limitation in the claims as to the language (claim 21).

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 22-24 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 22 claims DNA encoding biologically active fragments of the listed SEQ ID Nos. and DNA encoding immunogenic fragments of the listed SEQ ID Nos. This comes, of course from parts (c) and (d) of claim 21. The scope of the instant claims is not commensurate with the enablement of the instant disclosure, because practice of the claimed invention would require undue experimentation by an artisan of ordinary skill in the art. The instant specification is not enabling for biologically active fragments or immunogenic fragments.

The factors to be considered in determining whether undue experimentation is required are summarized in *re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). The court in *Wands* states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the

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presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In *Wands*, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (*Wands*, 8 USPQ2d 1406).

Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of *Wands* factors which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

In the instant case, it would not require undue experimentation to create pieces of DNA encoding fragments of polypeptide and expressing the DNA to make the. It would, however, require undue experimentation to test those fragments for any nonspecified biological activity or immunogenicity. Specifically, with regard to the Wands factors, (1) the quantity of experimentation is huge, since the number of possible biological activities is huge and the number of fragments is also very large, (2) the specification provides no guidance as to what biological activity is to be tested for and no guidance as to how to test for any particular biological activity or immunogenicity. It is clear from the prior art that the specification is correct to identify the claimed polypeptides as being involved in transport of proteins. However, there is no disclosure as to which portions of the proteins may be responsible for the activity. This type of guidance is needed for one of skill in the art to practice the invention. Continuing, (3) the specification is devoid of any working examples of biologically active fragments or immunogenic fragments, (4) the nature of the invention is the discovery of a new protein transport protein, (5) the state of the prior art is such that it seems reasonable to characterize the polypeptides as is done in the specification, (6) the relative skill of those in the art is extremely high, (7) it is totally unpredictable whether any fragment will retain any particular biological activity or be immunogenic and, (8) the claims are considered very broad with regard to the fragments with the claimed activity. Thus, the conclusion of undue experimentation is dictated.

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7. Claims 22-24 and 26 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As discussed above in the enablement rejection, the claims read on DNA encoding biologically active fragments and immunogenic fragments of the recited SEQ ID Nos. While applicants are in possession of all fragments since the entire sequences are disclosed, applicants have not demonstrated that they are in possession of fragments with the recited activities. There is no disclosure as to which portions of the polypeptides might be responsible for the transport activity and the specification demonstrates no other biological activity. Similarly, although epitopes may be on the order of six amino acids in size, not all six-amino-acid fragments would be expected to be immunogenic. There is no disclosure of the three-dimensional structure of the polypeptides and therefore no information as to which amino acids might be located on the outside of the protein molecule and, thus, be candidates for immunogenicity. To summarize, there is no structure-to-function relationship disclosed which would be necessary to establish possession of the claimed invention. Cancellation of the fragment language from the claims would overcome both rejections under the first paragraph of 35 USC 112.

Response to Arguments

8. Applicant's arguments filed November 10, 2003 have been fully considered but they are not persuasive. The rejection of claims 22 and 26 as indefinite has been maintained. Applicants argue that the rejection is improper in view of the incorrect restriction requirement. Since the restriction has not been determined to be incorrect the rejection stands. Should applicants petition and have the restriction altered, this rejection would become moot.

With regard to the anticipation rejection, applicants removed reference to SEQ ID Nos. 1 and 9 from the claims, thus rendering the rejection moot.

Allowable Subject Matter

9. Claims 28-31, 35, 36 and 39 are allowed. The prior art does not teach polynucleotides with the claimed sequences, the specification provides utility and enablement and, thus the above claims are deemed allowable.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S. F. Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Robert A. Wax', is positioned above the printed name.

Robert A. Wax
Primary Examiner
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